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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kerang Jiang

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

HENDERSON, RYAN N

ART UNIT

PAPER NUMBER

4137

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,485	Applicant(s) JIANG ET AL.	
	Examiner RYAN HENDERSON	Art Unit 4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/29/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

Background of the Invention:

"But flexible endoscopes can't bear with autoclaved way, also disinfection solution can't thoroughgoing flow into varied channels to sterilize wholly." (Page 1, Lines 12-14)

Summary of the invention:

"The flat channels is not easy to be bent and to block the flowing fluid-air also can be inflated and expanded into two cylinder channel cavities while flowing fluid-air flow into them. Said the structure of double cavity fluid-air channel" (Page 2, Lines 16-18)

"Inside of the anterior part of it which sheathes on the jet channel has not any septum" (Page 2, Lines 19-20)

Description of the Invention in Detail:

"To decrease the complication light, out of illumination outgoing light and reflect into observation system" (Page 6, Lines 6-7)

“The advantage of the flat channel is can not bent and can not be blocked by the flowing fluid-air, in addition, the closing channel which is not entered into by the flowing fluid-air only occupies less space” (Page 7, Lines 4-5)

“There are two incisions separating from the cavity wall, located at two sides of the certain section of the septum of round head 4.2, the septum section of round head 4.2 can be swung towards the left or right, to block the one of two cavities of the channel which flowing fluid needs not to flow into, prevent injecting fluid or air from back flowing into this one cavity” (Page 7, Lines 9-13)

These are only a few of the examples found in the specification, further inspection should be done by applicant. Appropriate correction is required

2. The disclosure is objected to because of the following informalities: When applicant is defining components of the endoscope system there needs to be a space between the component and the number its referring to. For example “The sucking channel adapter12.5” should be –The sucking channel adapter 12.5—.

Appropriate correction is required.

Claim Objections

3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

4. Claims 1-10 are objected to because of the following informalities:

In claim 1, applicant states “fluid-air exit and a sucking channel adapter are set on posterior endoscope, sheathe and connect a fluid-air channel adapter and sucking

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channel adapter of the disposal sheath". It seems as though the comma between "endoscope and "sheath" should be removed.

In claims 1, 2, 4-10, there requires a space between the term "claim" and the number for which that claim is dependent on. For example "according to claim1" should be --according to claim 1--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 recites the limitation "the capsule" in Line 2. There is insufficient antecedent basis for this limitation in the claim. This should be revised to --a capsule--. This format should be applied to the rest of the 112th rejections that lack antecedent basis below.

7. Claim 1 recites the limitation "the disposal channel" in Line 4. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 1 recites the limitation "the jet channel" in Line 8. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 1 recites the limitation "the end cap" in Line 9. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 1 recites the limitation "the three-way sealing cap" in Line 12. There is insufficient antecedent basis for this limitation in the claim.

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11. Claim 1 recites the limitation "the guide tube" in Line 12. There is insufficient antecedent basis for this limitation in the claim.

The following statements can't be understood due to poor wording:

Claim 2 states "the disposal channel connects in the endoscope channel at axial direction in anterior endoscope's site of the end cap, the end cap's surrounding is sheathed in anterior capsule"

Claim 4 states "the locking ring can make the capsule fix or loose the endoscope, and can be tight locked up or unlocked by handle"

Claim 5 states "the fluid-air channel can be made from double cavities channel, in its interior section which sheathe on the jet channel has no any septum" and "and at two sides of the later part of the round head respectively has on incision, making the septum swing towards any one direction, using for to block the channel which flowing fluid needs not to flow into"

Claim 6 states "the structure of two single cavity fluid-air channels via heat pressure become flat channel"

Claim 8 states "while the handle end face closes to the upper orifice of the three-way sealing cap" and "so that the tube core's lower end orientates to inferior to the second elastic sealing orifice" and "the tube core's lower end makes the posterior end of the disposal channel which is higher then the sucking channel orifice, being pressed to under the sucking channel orifice to prevent the sucking channel orifice from block"

Claim 9 states "V-shape electrical resistance thread is on one piece of two pieces of heat fusion forceps" and "wherein one piece can move to all the channel orifice"

8. The terms "permanent", "whole body" and "blocked V-shape" in claim 1 are relative terms, which renders the claim indefinite. The terms "permanent", "whole body" and "blocked V-shape" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. The terms "non-immune", "non-poisonous" in claim 4 are relative terms, which renders the claim indefinite. The terms "non-immune" and "non-poisonous" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. The terms "convenient", "back" and "later part" in claim 5 are relative terms, which renders the claim indefinite. The terms "convenient", "back" and "later part" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

11. The terms "nearing" and "flat" in claim 6 are relative terms, which renders the claim indefinite. The terms "nearing" and "flat" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

12. The terms "tight fixing" and "assistance" in claim 7 are relative terms, which renders the claim indefinite. The terms "tight fixing", "elastically sealing" and "assistance" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. The terms "quite large", "long orifice", "elastic sealing", "upper", "lower", "higher", "sited", "instantly", "tight contracted" and "right position" in claim 8 are relative terms, which renders the claim indefinite. The terms "quite large", "long orifice", "elastic sealing", "upper", "lower", "higher", "sited", "instantly", "tight contracted" and "right position" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

14. The terms "half bucket size" and "maximal" in claim 10 are relative terms, which renders the claim indefinite. The terms "half bucket size", "maximal" and "teeth locking" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3, 6, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi (US Patent No. 5,050,585).

In regard to claim 1, Takahashi discloses an endoscope system with a disposal sheath **(see Abstract)**, including an permanent endoscope **(entire system of Fig. 1)** which can be reused for many times and a disposal sheath **(10)**; wherein the capsule **(10a)** covers the outside of the endoscope as a part of the disposal sheath, connects the disposal channel which is inserted into the endoscope channel **(Fig. 1)**, both the anterior ends of the capsule and the disposal channel **(9)** are connected and joined in a whole body **(the capsule directly covers the disposal channel, Fig. 1)**; characterized in that a fluid-air exit **(19)** and a sucking channel adapter **(18)** are set on posterior endoscope, sheathe and connect a fluid-air channel adapter **(8)** and sucking channel adapter of the disposal sheath respectively, the fluid-air channel **(19)** can be a single cavity or double cavities channels; the fluid-air channel is set on outside of the endoscope **(The fluid-air channel is partially set on outside of the endoscope, Fig. 3)**; and parallel with the endoscope; the capsule, as the main body of the disposal sheath, covers the outside of the endoscope joining the jet channel **(11b, 11c)** and the fluid-air channel **(19)** via the end cap **(10b)** on the anterior end of capsule to form a whole body; the disposal sheath covers the outer surface of the endoscope body and the inner surface of the endoscope channel **(11a)** as well **(The disposal sheath is located around the exterior of the endoscope and therefore covers both the**

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endoscope body and the inner surface of the endoscope channel, Fig. 1); the posterior capsule connects a locking ring **(10A)**; after passing through the endoscope channel, the disposal channel is positioned in the three-way sealing cap **(14)** via the guide tube **(9)**; after the use, the channel orifice of the disposal channel can be heated and melted and cut off by a heat fusion forceps, to form a blocked V-shape **(The limitation regarding the use of forceps after the use of the system is regarded as intended use and is not part of the system. The disposal channel of Takahashi is capable of being heated and melted by forceps to create a V-shaped seal).**

In regard to claim 2, Takahashi teaches of the endoscope system with a disposal sheath, according to the claim 1, characterized in that the end cap is made of transparent material **(Col. 5, Lines 18-21)**, its inner end face's shape coincides with anterior end face of the endoscope body **(Fig. 1)**, the disposal channel **(11)** connects in the endoscope channel **(11a)** at axial direction in anterior endoscope's site of the end cap, the end cap's surrounding is sheathed in anterior capsule **(Fig. 1)**.

In regard to claim 3, Takahashi teaches of the endoscope system with a disposal sheath, according to the claim 2, characterized in that said the connection between the disposal channel and the end cap is via a channel seat which is produced on the disposal channel tip **(The guide tube (9) which holds the disposal channel (11) is loosely fit within the outer diameter of the end cap (10b), Col. 4, Lines 20-25).**

In regard to claim 6, Takahashi teaches of the endoscope system with a disposal sheath, according to the claim 1, the fluid-air channel **(19)** may be a single

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cavity structure which came from two single cavity channels (8a, 8b) join in together one channel at nearing the jet channel site, and the channel shape may be cylinder.

In regard to claim 7, Takahashi teaches of the endoscope system with a disposal sheath, according to the claim 1, characterized in that the three-way sealing cap (14) is made of elastic medical material **(The lower leg portion (15) of the connecting adapter (14) is made of a synthetic resin wherein the connecting adapter is attached to the control part (6) by the resilient force from the leg (15))**, its anterior end is fixed on the endoscope channel exit, its straight cavity is the way for inserting medical instrument and tight fixing the disposal channel (**Fig. 3**); its side exit is a sucking channel adapter (18) which connects the sucking channel, in the three-way sealing cap set three elastic sealing orifices **(the connecting adaptor (14) is used as a seal for the sucking adaptor, fluid air channel, and the mouthpiece (17) for inserting forceps)**, to elastically sealing the disposal channel at the guide tube's assistance.

In regard to claim 9 and 10, the use of forceps in the system is regarded as intended use and is not part of the endoscope system. Therefore, these claims are given no patentable weight.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) as applied to claim 1, and in view of DeStefano et al. (US Patent No. 6,282,442, hereinafter DeStefano).

In regard to claim 4, Since endoscopes are used in the medical field it's obvious that the capsule would have to be made out of a material that's nonpoisonous, non-immune and biocompatible. The capsule is designed to protect the endoscope and reduce friction when inserted into the patient making it obvious to lubricate the exterior of the capsule before performing an operation. Takahashi teaches of the capsule being made of a thin-walled cylinder using an elastic material, for example, silicone rubber **(Col. 3, Lines 40-43)**. Takahashi fails to teach of the locking ring containing teeth that can be locked or unlocked by handle.

DeStefano teaches of a multi-fit suction irrigation hand piece wherein C-clamps **(12a and 12b)** are used to restrict the flow of irrigant.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the sheathed endoscope of Takahashi and the locking ring of DeStefano to maintain a tight fit between the sheath and the guide tube while performing a surgical procedure.

19. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) as applied to claim 1, and in view of Shalit (US Patent No. 3,398,743).

In regard to claim 5, Takahashi teaches of the limitations of claim 1, but fails to teach of the fluid-air channel being a double cavity channel and containing a septum that's used as a valve.

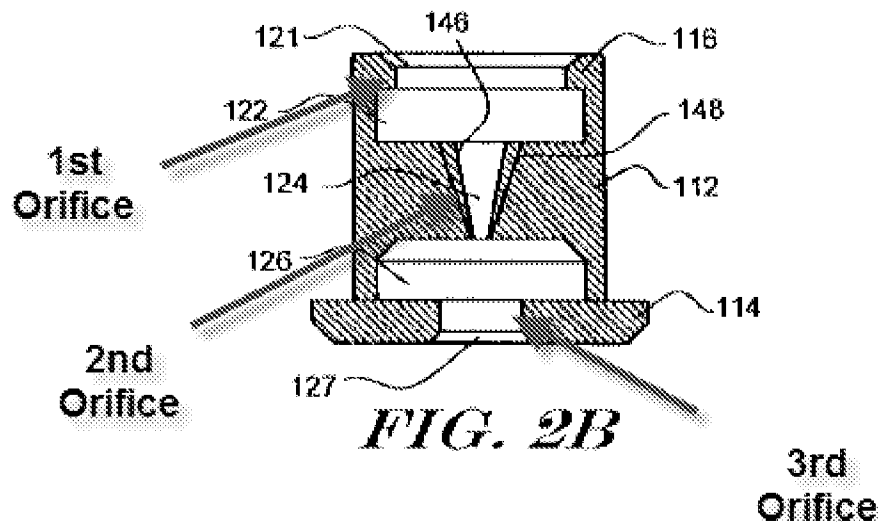
Shalit teaches of a closed system irrigating apparatus for viscus organs, wherein it comprises a pressure inlet tube **(48)** and a pressure outlet tube **(50)** and the tubes are separated by a septum **(12)** that can swing left and right as fluid flows through the tubes and a pair of check valves **(36, 38)** that prevent backflow of fluid **(Col. 1, Lines 29-44)**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the sheathed endoscope of Takahashi with the irrigating apparatus of Shalit to provide the endoscope with both inlet and outlet ports and prevent the two lines from contaminating each other.

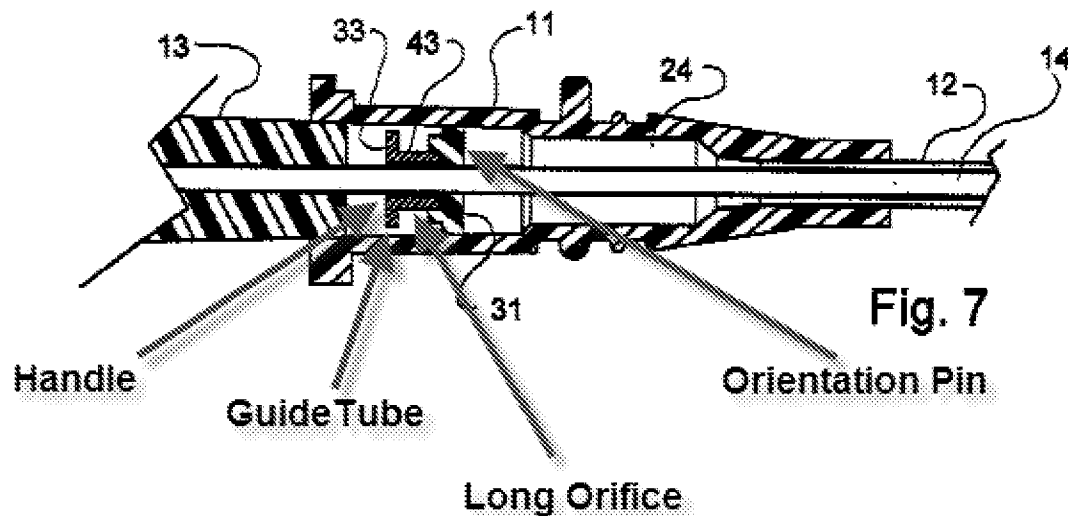
20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) as applied to claim 7 in view of Carrillo, JR. et al. (US Patent Application Publication No. 2003/0208104, hereinafter Carrillo) and Vaillacourt (US Patent Application Publication No. 2001/0053895)

In regard to claim 8, Takahashi teaches of the limitations of claim 7, but fails to teach of the three way sealing cap containing three elastic sealing orifices and the guide tube containing an orientation pin within the long orifice.

Carrillo teaches of a fluid seal for endoscopes wherein when placed into the three-way sealing cap **(14)** of Takahashi provides the structure required by the three-way sealing cap of applicant. Carrillo's sealing cap contains three sealing orifices **(see Fig. 2B below)**, wherein the guide tube can be placed within the three way seal.



Vaillancourt teaches of a bloodless catheter wherein a guide tube (**see Fig. 7 below**) comprises an orientation pin (**see Fig. 7 below**) that is inserted into a hub (**11**) and helps facilitate the passage of a needle hub (**13**) through the guide tube. The guide tube of Vaillancourt could be used with the 3-way seal provided by Carrillo and Takahashi by inserting the guide tube into the 3-way seal and the orientation pin would be pushed over the 3rd elastic sealing orifice (**see Fig. 2B above**).



It would have been obvious by one of ordinary skill in the art at the time of the invention to provide the sheathed endoscope of Takahashi with the 3-way fluid seal of Carrillo and the guide tube of Vaillancourt to provide seals preventing the endoscope from becoming contaminated allowing devices to be used multiple times.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN HENDERSON whose telephone number is (571)270-1430. The examiner can normally be reached on M-F 7:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 4137
7/6/2009

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4137